K063347

ADMIN 3.0 AxSYM® Anti-CCP 510(K) SUMMARY

MAR 2 0 2007

(Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of CFR.

Submission Date: 03 Nov 2006

Dr Erica Conway

Regulatory Affairs Manager

Axis-Shield Diagnostics, Ltd.

The Technology Park

Dundee DD2 1XA, Scotland, UK

Device Name: AxSYM® Anti-CCP

Reagents:

Classification Name: Antibodies, ANTI-CYCLIC CITRULLINATED PEPTIDE (CCP)

Trade Name: AxSYM® Anti-Cyclic Citrullinated Peptide (Anti-CCP)

Common Name: Anti-CCP test

Governing Regulation: 866.5775

Device Classification: Class II

Classification Panel: Immunology

Product Code: NHX

Calibrators:

Classification Name: Calibrator, Secondary

Trade Name: AxSYM® Anti-CCP Standard Calibrators

Common Name: Calibrator

Governing Regulation: 862.1150

Device Classification: Class II

Classification Panel: Clinical Chemistry

Product Code: JIT

Controls:

Classification Name: Single (specified) analyte controls (assayed and unassayed)

Trade Name: AxSYM® Anti-CCP Control

Common Name: Control

Governing Regulation: 862.1660

Device Classification: Class I

Classification Panel: Clinical Chemistry

Product Code: JJX

Legally marketed device to which equivalency is claimed:

DIASTAT™ Anti-CCP Assay (K023285)

Intended Use of Device:

AxSYM® Anti-CCP is a Microparticle Enzyme Immunoassay (MEIA) for the semi-quantitative determination of the IgG class of autoantibodies specific to cyclic citrullinated peptide (CCP) in human serum and plasma on the AxSYM System. Detection of anti-CCP antibodies is used as an aid in the diagnosis of Rheumatoid Arthritis (RA) and should be used in conjunction with other clinical information. Autoantibody levels represent one parameter in a multicriterion diagnostic process, encompassing both clinical and laboratory-based assessments.

The AxSYM® Anti-CCP Standard Calibrators are for the standard calibration of the AxSYM System when used for the semi-quantitative determination the IgG class of autoantibodies specific to cyclic citrullinated peptide (CCP) in human serum and plasma.

The AxSYM® Anti-CCP Controls are for the use in quality control to monitor the accuracy and precision of the AxSYM Anti-CCP assay when used for the semi-quantitative determination of the IgG class of autoantibodies specific to cyclic citrullinated peptide (CCP) in human serum and plasma on the AxSYM System.

Description of Device:

AxSYM Anti-CCP is based on Microparticle Enzyme Immunoassay (MEIA) technology. The AxSYM Anti-CCP reagents and sample are pipetted in the following sequence:

SAMPLING CENTER

- Sample and all AxSYM Anti-CCP reagents required for one test are pipetted by the Sampling Probe into various wells of a Reaction Vessel (RV).
- AxSYM Line Diluent and sample are pipetted into the Incubation Well of the RV.
- The AxSYM Anti-CCP Sample Diluent and diluted sample are pipetted into the Sample Well of the RV.
- The AxSYM Anti-CCP Matrix Cell Blocker is pipetted into the Buffer Well of the RV.
- The AxSYM Anti-CCP Mouse Anti-Human IgG:Alkaline Phosphatase Conjugate is pipetted into Reagent Well 3 of the RV.
- AxSYM Line Diluent and CCP-Coated Microparticles are pipetted into Reagent Well 2 of the RV.

- A reaction mixture is formed by combining diluted sample and diluted microparticles coated with CCP in Reagent Well 1 of the RV.
- When anti-CCP antibody is present in the sample, it binds to the CCP-Coated Microparticles, forming antigen-antibody complexes on the microparticles.

The RV is immediately transferred into the Processing Center. Further pipetting is done in the Processing Center by the Processing Probe.

PROCESSING CENTER

- An aliquot of Matrix Cell Blocker is transferred to the Matrix Cell.
- An aliquot of the reaction mixture, containing microparticles and bound antigen-antibody complex, is transferred to the Matrix Cell. The microparticles bind irreversibly to the glass fiber matrix.
- The Matrix Cell is washed to remove materials not bound to the microparticles.
- The AxSYM Anti-CCP Mouse Anti-Human IgG:Alkaline Phosphatase Conjugate is dispensed onto the Matrix Cell and it binds with the antigen-antibody complexes.
- The Matrix Cell is washed to remove conjugate not bound to the microparticles.
- The substrate, 4-Methylumbelliferyl Phosphate, is added to the Matrix Cell. The alkaline phosphatase-labeled conjugate catalyzes the removal of a phosphate group from the substrate, yielding the fluorescent product, 4-Methylumbelliferone. This fluorescent product is measured by the MEIA optical assembly.

Comparison of Technological Characteristics:

AxSYM Anti-CCP is based on Microparticle Enzyme Immunoassay (MEIA) technology.

DIASTAT™ Anti-CCP is an enzyme-linked immunosorbent assay (ELISA).

Summary of Non-Clinical Performance:

The AxSYM® Anti-CCP assay is substantially equivalent to the DIASTAT™ Anti-CCP assay in terms of precision, linearity, interferences and stability as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The AxSYM® Anti-CCP assay demonstrated substantially equivalent performance to the DIASTAT™ Anti-CCP indicated by a method comparison with 97.3 % concordance for all samples tested. A Receiver Operator Characteristic (ROC) curve analysis determined that the DIASTAT Anti-CCP and the AxSYM Anti-CCP assays' Area Under the Curve are 0.870 and 0.875, respectively. This analysis indicates that the two assays are comparable with respect to cut-off and specimen values.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Axis-Shield Diagnostics Ltd
c/o Ms. Erica Conway
Regulatory Affairs Manager
The Technology Park
Dundee, Scotland DD2 1XA
United Kingdom

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Re: k063347
Trade/Device Name: AxSYM® Anti-CCP Reagent Kit, AxSYM® Anti-CCP Standard Calibrator Kit and AxSYM® Anti-CCP Control Kit
Regulation Number: 21 CFR 866.5775
Regulation Name: Rheumatoid factor immunological test system
Regulatory Class: Class II
Product Code: NHX, JIX, JJY
Dated: February 23, 2007
Received: February 26, 2007

Dear Ms. Conway:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to

begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

ADMIN 5.0 Product Classification - Indications for Use Statement

510(k) Number (if known): K063347

Device Name: AxSYM® Anti-CCP Reagents, AxSYM® Anti-CCP Standard Calibrators (A-F) and AxSYM® Anti-CCP Controls (Positive and Negative)

Indications for Use:

Reagents

AxSYM® Anti-CCP is a Microparticle Enzyme Immunoassay (MEIA) for the semi-quantitative determination of the IgG class of autoantibodies specific to cyclic citrullinated peptide (CCP) in human serum and plasma on the AxSYM System. Detection of anti-CCP antibodies is used as an aid in the diagnosis of Rheumatoid Arthritis (RA) and should be used in conjunction with other clinical information. Autoantibody levels represent one parameter in a multicriterion diagnostic process, encompassing both clinical and laboratory-based assessments.

Calibrators

The AxSYM® Anti-CCP Standard Calibrators are for the standard calibration of the AxSYM System when used for the semi-quantitative determination the IgG class of autoantibodies specific to cyclic citrullinated peptide (CCP) in human serum and plasma.

Controls

The AxSYM® Anti-CCP Controls are for the use in quality control to monitor the accuracy and precision of the AxSYM Anti-CCP assay when used for the semi-quantitative determination of the IgG class of autoantibodies specific to cyclic citrullinated peptide (CCP) in human serum and plasma on the AxSYM System.

For in vitro diagnostic use.

Prescription Use	X	OR Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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